Claim 17. (currently amended) The method of claim 16 wherein said [fragment] <u>probe</u> comprises a sequence of at least 10 consecutive nucleotides [unique to SEQ ID NO: 1].

## Remarks:

Claims 2, 12-15 have been cancelled. Claim 1, 16 and 17 have been amended. Support for these amendments may be found in the specification at the following pages; no new matter has been added:

Claim 1 – support at page 4, lines 17-20, page 10, lines 17-18 and page 11, lines 13-17.

Claim 1 has been amended to more particularly recite the invention by adding language referring to detection of polynucleotides in a breast sample, utilizing a probe which comprises at least 10 consecutive nucleotides in length and quantifying suppressed hybridization in control levels from surrounding breast samples to indicate the presence of a breast tumor.

Claims 1, 7 and 16 have been amended to delete recitation of "stringent" or "highly stringent" conditions.

## Rejection under 35 USC 102(e)

Claim 1 and 2 have been rejected under 35 USC 102(e) as being anticipated by either Band or Vogelstein. The Examiner maintains Band discloses and claims the methods of Applicant's invention because Band discloses a method for detection of breast cancer in breast tissue with a probe that would comprise a fragment of SEQ ID NO:1 and wherein a decrease in hybridization indicates malignancy in a patient. Applicants respectfully submit the amendments made herewith to Claim 1 are of sufficient scope to avoid anticipation by the Band (SEQ ID 1 and 2) and Vogelstein references. As such, Applicants respectfully request that this rejection be withdrawn.

Claims 1 and 2, 12-15 have been rejected under 35 US 102(e) in view of Papsidero et al., US Patent 6,306,563. Applicants respectfully submit the amendments made herewith to Claim 1 avoids anticipation by Papsidero. Papsiderto teaches detecting breast tumors based on the presence of the MACK chemokine in sera or tissue samples from patients. The amendments to Claim 1 clearly teach Applicants' novel invention, i.e., that **under expression** in breast tissue provides the accurate diagnostic of breast cancer in a patent, not the increased levels taught by Papsidero.

Rejections under 35 USC 112, second paragraph

Claims 1, 2 and 7-17 are rejected under 35 USC 112, second paragraph as being indefinite for reciting "stringent conditions" or "highly stringent conditions" which the Examiner contends are not described in the specification in such a way as to define these terms. The Examiner alleges the specification does not describe the full breadth of what is encompassed by these terms and although the specification provides one algorithm for determining "highly stringent" conditions, it does not provide any other algorithm that may be used or how to determine "stringent" conditions.

Applicants have herein amended claims 1, 7, and 16 to eliminate recitation of "highly stringent" or "stringent" conditions. Applicants submit that as amended herewith, the Claim 1, 7, 16 and the claims dependent thereon comply with 35 USC 112, second paragraph, and respectfully request that this rejection be withdrawn.

In view of the foregoing, Applicants have amended the claims to place the application in condition for Allowance. Applicants respectfully request that a timely Notice of Allowance be issued in this case.

If there are any fees due in connection with this communication, including any fees for a required extension of time, such an extension is requested and the Commissioner is authorized to charge the fees to Deposit Account No. 19-0134 in the name of Novartis.

Respectfully submitted,

Attorney for Applicants

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Date: 2-3-04